RECEIVED AT DRUG SAFETY SURVEILLANCE

18-MAR-1998-0280

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Individual Safety Report

3057284-4-00

DA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	or 23	☐ female ☒ male	UNK lbs ____ kgs
	Date of birth: [redacted]		

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcome attributed to adverse event (check all that apply)

- ☒ death 4/24/95 (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization-initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
4/16/95	03/02/98

5. Describe event or problem

THERAFLU - Unknown Formula: 7/22/97 - Report from attorney indicates a 23 year old male was prescribed acetaminophen and codeine about 3/13/95 for an injured right hand and ingested the prescribed 20 tabs over one weeks time. Consumer experienced cold/flu and ingested Extra-Strength Tylenol 4/14/95-4/16/95 and Theraflu 4/15/95-4/16/95. On 4/16/95 consumer complained of fever, back and neck pain, right upper quadrant tenderness, facial rash, voiding tea colored urine, and light colored stool, and was admitted to [redacted] Hospital. Consumer was diagnosed with potential infectious or chemical acute hepatitis. Tissues, blood, fluids, stomach, liver and other bodily organs contained levels of acetaminophen suggesting toxicity. On 4/16/95 while hospitalized, consumer was given Tylenol 975mg. On 4/18/95 consumer was transferred to [redacted] Hospital for his worsening condition and possible liver transplant. On 4/19/95

CONTINUED

6. Relevant tests/laboratory data, including dates

4/16/95 - tissues, blood, fluids, stomach, liver and other bodily organs contain levels of acetaminophen suggesting toxicity. Calculated acetaminophen ingestion 7.5-10g (15-20 500mg tabs), acetaminophen level 27. Autopsy Report notes a history of alcohol

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

3/95 - physical injury to right hand treated with acetaminophen and codeine;
4/14/95-4/16/95 - cold/flu treated with Extra-Strength Tylenol.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 THERAFLU-UNKNOWN-NvCH
#2 TYLENOL III-ACETAMINOPHEN/CODEINE-MCNEIL PH.

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 Unknown/Unk/PO	#1 4/15/95 - 4/16/95
#2 Unknown/Unk/PO	#2 4/1/95 - 4/10/95

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 cold/flu symptoms	#1 ☐ yes ☐ no ☒ doesn't apply
#2 right hand injury	#2 ☐ yes ☐ no ☒ doesn't apply

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 Unknown	#2 Unknown

9. NDC # — for product only (if known)

N/A

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☒ doesn't apply

10. Concomitant medical products and therapy dates (exclude treatment of event)

Extra-Strength Tylenol

G. All manufacturers

1. Contact office — name/address (& mfring site for devices)

Novartis Consumer Health, Inc.
560 Morris Ave.
Summit, NJ 07901-1312

2. Phone number: 908-598-7730

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☒ other: FDA # attorney

4. Date received by manufacturer (mo/day/yr): 02/19/98

5. (A) NDA # N/A
IND # ____
PLA # ____
pre-1938 OTC product ☐ yes ☒ yes

6. If IND, protocol #: N/A

7. Type of report (check all that apply)

- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☐ initial ☒ follow-up # 1

8. Adverse event term(s)

HEPATITIS

9. Mfr. report number: 0149331A

E. Initial reporter

1. Name, address & phone #

Mr. [redacted] Esq.
[redacted] Building
[redacted] Street

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
☐ yes ☒ no	attorney	☐ yes ☐ no ☒ unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile of FDA Form 3500A

RECEIVED AT DRUG SAFETY SURVEILLANCE
18-MAR-1998-0281

Form : I Individual Safety Report
3057284-4-00

Novartis Consumer Health, Inc.
MFR Report # 0149331A
Patient Initials: [redacted]

CONTINUATION OF B5: consumer lapsed into coma and on 4/24/95 died from liver failure. Additional information requested.

3/2/98 - Follow-up from lawyer [redacted] Esq.) indicates patient injured his wrist 3/95 and was prescribed Tylenol III (acetaminophen with codeine) by his doctor, which was taken 4/1/95 to 4/10/95. Patient's ER records from [redacted] Hospital record the patient's acetaminophen ingestion at 7.5-10g (15-20 500mg tablets), and an acetaminophen level of 27 (no units given). According to the lawyer, the Autopsy Report notes a history of alcohol abuse and a positive barbiturate screen.

Novartis Consumer Health, Inc.
MFR Report # 0149331A
Patient Initials: [redacted]

Individual Safety Report
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C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known)
#3 EXTRA-STRENGTH TYLENOL-MCNEIL CONSUMER PROD. CO.
#4

2. **Dose, frequency & route used**
#3 Unknown/Unk/PO
#4

3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
#3 4/14/95 - 4/16/95
#4

4. **Diagnosis for use** (indication)
#3 cold/flu symptoms
#4

5. **Event abated after use stopped or dose reduced**
#3 ☐ yes ☐ no ☒ doesn't apply
#4 ☐ yes ☐ no ☒ doesn't apply

6. **Lot #** (if known)
#3 Unknown
#4

7. **Exp. date** (if known)
#3 Unknown
#4

8. **Event reappeared after reintroduction**
#3 ☐ yes ☐ no ☒ doesn't apply
#4 ☐ yes ☐ no ☒ doesn't apply

9. **NDC # — for product only** (if known)
N/A

1. **Name** (give labeled strength & mfr/labeler, if known)
#5
#6

2. **Dose, frequency & route used**
#5
#6

3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
#5
#6

4. **Diagnosis for use** (indication)
#5
#6

5. **Event abated after use stopped or dose reduced**
#5 ☐ yes ☐ no ☐ doesn't apply
#6 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
#5
#6

7. **Exp. date** (if known)
#5
#6

8. **Event reappeared after reintroduction**
#5 ☐ yes ☐ no ☐ doesn't apply
#6 ☐ yes ☐ no ☐ doesn't apply

9. **NDC # — for product only** (if known)

1. **Name** (give labeled strength & mfr/labeler, if known)
#7
#8

2. **Dose, frequency & route used**
#7
#8

3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
#7
#8

4. **Diagnosis for use** (indication)
#7
#8

5. **Event abated after use stopped or dose reduced**
#7 ☐ yes ☐ no ☐ doesn't apply
#8 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
#7
#8

7. **Exp. date** (if known)
#7
#8

8. **Event reappeared after reintroduction**
#7 ☐ yes ☐ no ☐ doesn't apply
#8 ☐ yes ☐ no ☐ doesn't apply

9. **NDC # — for product only** (if known)